A comparison of the clinical use of the Laryngeal Tube S (TM) and the ProSeal (R) Laryngeal Mask Airway by first-month anaesthesia residents in anaesthetised patients

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Published in:
Anaesthesia

DOI:
10.1111/j.1365-2044.2007.05073.x

Anaesthesia, 2007, **62**, pages 723–727 doi:10.1111/j.1365-2044.2007.05073.x

APPARATUS

A comparison of the clinical use of the Laryngeal Tube S™ and the ProSeal® Laryngeal Mask Airway by first-month anaesthesia residents in anaesthetised patients*

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Summary

The Laryngeal Tube S™ and the LMA-ProSeal® are supraglottic instruments with an improved airway seal and a drainage tube to protect against regurgitation and to facilitate passage of a gastric tube. We compared the feasibility of these two instruments in a randomised, controlled clinical trial. One hundred and sixty patients were randomly allocated to undergo insertion of a Laryngeal Tube S ($n = 82$) or an LMA-ProSeal ($n = 78$). All insertions were carried out by first-month anaesthesia residents. Success rates were not significantly different: Laryngeal Tube S 89%, LMA-ProSeal 95%. There was also no significant difference in leak pressure or insertion time. Insertion time decreased significantly when we compared the first with the last 10 insertions. Gastric tube placement was successful in all patients in the Laryngeal Tube S group, but failed in 12 patients in the LMA-ProSeal group ($p < 0.001$). Dysphagia was reported by 22% of Laryngeal Tube S group and 3% of LMA-ProSeal group ($p = 0.001$). These findings demonstrate the applicability of the devices and a learning effect in the hands of anaesthesia residents with limited experience.

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**This study was performed at the Department of Anaesthesiology of the University Medical Centre Groningen.*
Accepted: 27 February 2007

Since its introduction in 1983, the Laryngeal Mask Airway (LMA) has established an important role in airway management. Originally, it was designed as an alternative to facemask ventilation and tracheal intubation. Over the years, it has become a rescue device in cannot-intubate-cannot-ventilate situations. Even though the LMA has been a major advance in airway management, there is an ongoing search for improvement.

One main goal in this search is to increase the laryngeal seal, permitting safe use of positive pressure ventilation without leakage into the mouth or stomach. A second goal is to protect against regurgitation and gastric insufflation by separating the respiratory from the gastro-intestinal tracts by a drainage tube. Recently, two newly developed devices providing these improvements were introduced into clinical practice. One device is the Laryngeal Tube S™ (LTS) (VBM Medizintechnik Gmbh, Sulz, Germany). It is a double lumen tube wherein the larger lumen is used for ventilation and the other lumen can be used for drainage of gastric fluid and for gastric tube placement. The LTS has an oropharyngeal and an oesophageal low-pressure cuff, with two main ventilation apertures placed between them, which are positioned at the level of the vocal cords [1].

The other device is the ProSeal® Laryngeal Mask Airway (LMA-ProSeal) (Laryngeal Mask Company, Henley-on-Thames, UK). It has a modified cuff at the dorsal side, improving the seal around the glottis by the

cuff itself and by changing the shape of the device once in situ. It has a drain tube added to provide a bypass channel for regurgitated fluid. This channel also facilitates passage of a gastric tube [2]. Both latex-free instruments are inserted without direct visualisation of the glottis in anaesthetised patients.

This study was designed to compare the clinical feasibility of these two devices in the hands of inexperienced users in anaesthetised patients. We hypothesised that the LTS and the LMA-ProSeal perform similarly, concerning achievement of an adequate airway with positive pressure ventilation without leak. Additionally, we studied the number of insertion attempts, time needed for insertion, whether a gastric tube could be inserted, learning effect, haemodynamic and respiratory response to insertion, side-effects and complications.

Methods

After obtaining the approval of the Hospital Ethics Committee and written informed consent from the patients, we studied 160 ASA physical status I–II patients, aged 18 years and older, scheduled for routine elective surgery suitable for usage of an LMA in a randomised controlled clinical trial. Patients were not included if they had any abnormality of neck, upper respiratory or alimentary tract, if they were at risk of aspiration, or if there was no access to the head during surgery.

Patients were randomly allocated in block fashion: in each 10 consecutive patients five were randomly assigned to the LTS and five to the LMA-ProSeal group. Standard monitoring, including ECG, NIBP, S_pO_2 and $F_{\acute{E}}CO_2$, was continuously performed. After pre-oxygenation with 100% oxygen for 3 min, anaesthesia was induced with remifentanil 25 $\mu g.kg^{-1}.h^{-1}$ followed by propofol 2–4 $mg.kg^{-1}$. The patient's lungs were ventilated using a facemask until adequate jaw relaxation needed for insertion was achieved. Anaesthesia was continued with propofol and remifentanil as required. Ventilation was with oxygen-enriched air F_IO_2 0.3.

The airway device to be used was revealed just prior to insertion. Size selection, insertion technique and fixation of the device were according to the manual [3, 4]. In the LMA-ProSeal group, the introducer was used for insertion. To prevent any unequal influence on the performance of both devices, all insertions were carried out by three residents, without experience in using supraglottic devices. They had been instructed by the manufacturer's manual and video, and had inserted both instruments 10 times on a manikin before the study started.

After insertion, the cuff was inflated, the breathing system was connected and the adequacy of ventilation assessed. Adequate ventilation was defined as tidal volume $> 6\ ml.kg^{-1}$ with pressure controlled ventilation 17/0, frequency 10 $breaths.min^{-1}$, I : E = 1 : 1.5. If placement was not successful within three attempts or if adequate ventilation was not achieved, the case was classified as a failure, the study protocol was abandoned and appropriate airway management was taken care of by the responsible anaesthetist.

If insertion was successful and ventilation was adequate, intra-cuff pressure was measured and controlled with a cuff pressure gauge (VBM Medizintechnik GmbH) and set and maintained at 60 cmH_2O. The leak pressure was determined by closing the expiratory valve of the breathing system, recording the pressure at which either an audible leak through the mouth or to the stomach occurred (by auscultation), or the level at which no further increase of pressure could be reached [5]. To prevent barotrauma, the airway pressure was not allowed to exceed 40 cmH_2O. Thereafter, a gastric tube was inserted. Finally, in the recovery room, patients were assessed for any mucosal lesions and dysphagia.

The primary outcome variables were successful device placement as judged by achieving adequate ventilation, and the corresponding leak pressure. Secondary outcome variables were number of insertion attempts, insertion time needed (measured from picking up the instrument until confirming adequate ventilation), learning effect, haemodynamic and respiratory response to insertion, whether a gastric tube could be inserted and the incidence of side-effects or complications.

The study was designed to test equivalence of the two devices on the primary outcome variables. We considered a difference of 10% in achieving adequate ventilation and a difference in leak pressure of $> 5\ cmH_2O$ as clinically significant. To detect such a difference between the two instruments, we needed a sample size of 64 patients for each instrument ($\alpha = 0.05$, power 0.80). Taking into account the logistical restraints, our aim was to assign about 50–60 patients to each of the three residents.

Data are summarised as mean (SD), median (IQR), or as counts and percentages. For comparison of the two groups, we used the *t*-test for independent samples, Mann–Whitney *U*-test, the Chi-squared test or Fisher's exact test. For the primary outcome variables, this comparison is supplemented with confidence intervals. A p value of 0.05 or less was considered significant. The joint effect of explanatory variables on the success rate of intubation at the first attempt was also evaluated by logistical regression. For the learning effect, we compared the first with the last 10 insertions of each novice. We used SPSS 12.0.1 for Windows© (SPSS Inc., Chicago, IL, USA) to carry out the computations.

Results

The study lasted 5 months and 160 patients were included. Eighty-two patients were assigned to the LTS group and 78 to the LMA-ProSeal group. Patient characteristics are shown in Table 1. There were no differences between the groups.

The outcome data are summarised in Table 2. There was no significant difference in success rate after either one or three insertion attempts between the LTS (68% and 89%) and the LMA-ProSeal (73% and 95%). In logistical regression analysis with success at first attempt as the outcome variable, the only significant variables were residents and ASA physical status (the success rate was higher in ASA II than in ASA I patients). The success rates at first attempt of each of the residents for both devices were 47%, 72% and 93% ($p < 0.001$). At three attempts, the success rates were 87%, 88% and 100% ($p = 0.027$). Correcting for these two variables did not reveal any differences between the two devices.

Table 1 Patients' characteristics. Date presented as mean (SD) or number of patients.

Variable	LTS $n = 82$	LMA ProSeal $n = 78$
Age; years	40 (12)	44 (14)
Height; cm	176 (11)	176 (10)
Weight; kg	77 (14)	80 (15)
Body mass index; $kg.m^{-2}$	24.8 (3.7)	25.5 (3.8)
Sex; Male/Female	37/45	39/39
ASA; I/II	53/29	41/37
Mallampati score; 1/2/3	65/16/1	60/17/1
Mouth opening; cm	5 (0.6)	5 (0.6)
Dentition own/partial/ edentulous	70/5/6	58/7/13
Intubators: A/B/C (*n*)	29/25/28	26/25/27

Table 2 Assessment of device placement. Data presented as median ($P_{25} - P_{75}$), mean (SD) or number (proportion).

Variable	LTS $n = 82$	LMA ProSeal $n = 78$	p
Insertion attempts; *n*			
1	56 (68%)	57 (73%)	0.61
2	72 (88%)	69 (88%)	1
3	73 (89%)	74 (95%)	0.25
Failures; *n* (%)	9 (11%)	4 (5%)	
Gastric tube placement; *n*			
Success/Failure	73/0	62/12	< 0.001
Adequate airway and gastric tube			
Success (%)	73 (89%)	62 (80%)	0.127
Insertion time; s	55 (42–80)	53 (45–69)	0.56
Leak pressure; cmH_2O	25 (20–31) ($n = 75$)	26 (20–30) ($n = 74$)	0.86

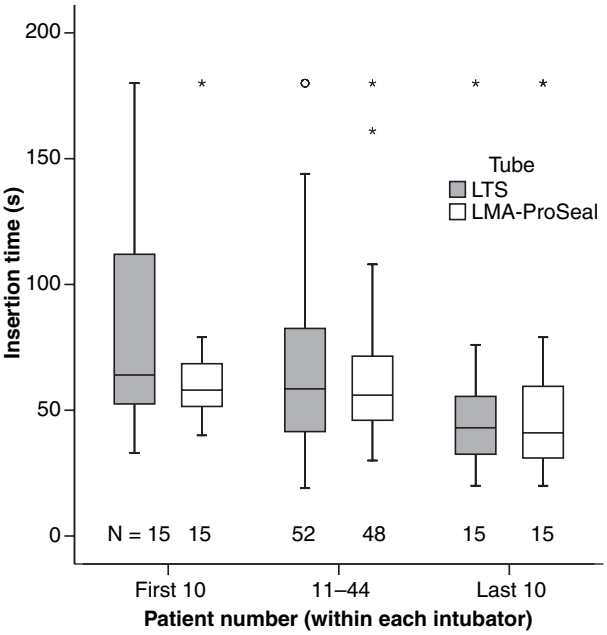

Figure 1 Insertion time during three consecutive phases of the study. Dark boxes, LTS; light boxes, LMA-ProSeal. Maximum time 180 s. First 10 insertions, five LTS and five LMA-ProSeal for each intubator, showed a median insertion time 62.5 s. This decreased significantly to a median of 42.5 s for the last 10 insertions ($p < 0.001$).

There were no differences in the times to achieve adequate ventilation and in the leak pressures of both devices.

Gastric tube placement was successful in all patients in whom the LTS was placed successfully, whereas in the LMA-ProSeal group, the placement failed in 12 out of 74 of such patients ($p < 0.001$). Success rates for both goals, adequate ventilation and gastric tube insertion, were 89% for the LTS and 80% for the LMA-ProSeal ($p = 0.127$, 95% CI for the difference − 2% to 21%).

The learning effect, regarding the time needed for insertion, decreased significantly from a median 62.5 s for the first 10 patients of each intubator to a median 42.5 s for the last 10 patients ($p < 0.001$ by Mann–Whitney test) (Fig. 1).

There were no differences in the haemodynamic and respiratory responses to insertion between the LTS and LMA-ProSeal groups (data not presented). Oxygen saturation never dropped below 90%.

Data on complications and side-effects are summarised in Table 3. Dysphagia was reported by 22% of LTS cases and by 3% of LMA-ProSeal cases ($p = 0.001$). The incidence of dysphagia also varied, depending on the resident, from 2.2% to 18.7% ($p = 0.027$, Fisher's exact test). Two cases were complicated by lesions of the

Table 3 Number of patients with complications and side-effects.

	LTS $n = 73$	LMA ProSeal $n = 74$	p
Dysphagia	16	2	< 0.001
Lesion of lingual frenulum	0	2	
Bradycardia	0	1	
Glottic closure	0	1	
Aspiration	0	0	
Luxation	1	2	

lingual frenulum while introducing the LMA-ProSeal. In both cases, the lesions resolved spontaneously within 10 days. In another case, a bradycardia of less then 30 beats.min^{-1} occurred after insertion of the LMA-ProSeal. After removal of the device, the heart rate recovered to 55 beats.min^{-1}. Upon renewed insertion, the heart rate remained within normal values. One LMA-ProSeal case was complicated by an initial total inability to ventilate the patient's lungs, which resolved after lowering the intra-cuff pressure to 60 cmH_2O [6]. Luxation of the device was seen in three cases, one LTS and two LMA-ProSeal. There were no signs of aspiration during the study. In one LMA-ProSeal case, we found bile fluid in the drain tube, but not in the airway tube or mask of the instrument, indicating that it had prevented aspiration.

Discussion

This prospective randomised study, designed to compare clinical performance of two devices in the hands of inexperienced users in anaesthetised patients, demonstrates that the LTS and the LMA-ProSeal perform similarly with regards to successful placement, as judged by achieving adequate ventilation within three insertion attempts and in corresponding similar leak pressures.

In our study, we achieved adequate ventilation in 89% of insertions in the LTS group and in 95% of insertions in the LMA-ProSeal group. In the literature, these rates for both the LTS and the LMA-ProSeal vary depending on the investigators: for the LTS it is between 80% and 100% first time success rate and between 94% and 100% within three attempts [1, 7, 8]; and for the LMA-ProSeal, it is between 76% and 100% first time and between 81% and 100% overall [8–14].

Although our residents felt familiar with the instruments after instruction and training on a manikin, their experience remained limited compared to the clinicians' in previous studies. The limited experience may also explain the significant difference in success rates between the residents, especially at the first attempt. As might be expected, these differences disappear with increasing experience.

No additional tools are needed for insertion of the LTS. The LTS is angulated, directing the tip to the dorsal pharynx [1]. During seven of the very first 10 LTS cases, we found that insertion failed, as the tip of the instrument impinged on the dorsal hypopharynx. This problem was solved by extension of the neck and lifting the jaw or pushing the patient's tongue aside. This manoeuvre is not mentioned in the manual but was suggested by an expert on the LTS. Probably, the insertion success rate for the LTS would have been higher, especially for the first intubator and overall, if we had used this modified technique for all patients.

The time to establish adequate ventilation was comparable in both groups: 55 and 53 s, respectively. Insertion time varied widely. We observed a significant decrease in time to establish adequate ventilation when we compared the first with the last 10 insertions.

Our first-month residents had no previous experience in using laryngeal mask airways. In this respect the study differs from all other studies of these devices carried out in anaesthetised patients. Prior experience may give the LMA-ProSeal an advantage. To exclude this in our study, we chose to compare clinical experiences of both instruments in the hands of first-month residents in anaesthesia.

Our median leak pressure is lower than reported in previous studies. Apart from the intubators having less experience, the greater height of the patients in our study is the only striking difference with other studies.

In 12 cases in the LMA-ProSeal group, the gastric tube could not be inserted. Malposition, in which the tip is folded posteriorly and thus obstructs passage of a suctioning catheter, might be the explanation. This results in failure of the drainage tube to perform its intended function, but it may have no effect on the seal or ventilatory function [15].

Patients in the LTS group experienced dysphagia significantly more frequently than did patients in the LMA-ProSeal group. The reported incidence of 3% for the LMA-ProSeal was very low compared to other studies, in which it varied from 12 to 26% [8, 10, 12, 13]. We found that the incidence was related to the resident inserting the device.

Our study has some limitations. Firstly, for logistical reasons, the first and the third intubator could not finish their sixth group of 10 patients; this explains the difference in numbers randomised to LTS and LMA-ProSeal groups. Secondly, as data were collected unblinded, some bias is possible. Thirdly, not only were the intubators inexperienced, but none of the authors had extensive experience with either device. We found an

increase in success rate between the first and the third resident. It is very likely that we would have scored higher results if we had started the study after acquiring ample experience ourselves. Fourthly, as we did not control the position of the devices with a fibrescope, we were unable to confirm whether inadequate ventilation was due to malposition of the device or another reason.

We conclude that the LTS and the LMA-ProSeal perform similarly in achieving adequate ventilation and in corresponding leak pressures. We discovered a learning effect with time to establish an adequate airway within 50 insertions per intubator. Dysphagia occurred significantly less frequently in the LMA-ProSeal group.

Acknowledgements

The authors would like to thank Ellen Weelink, Iva Ptackova and Bart Ramaker for their enthusiasm and great efforts in inserting the devices in their patients, and all the workers of the department 'ODBC' of the University Medical Centre Groningen for their assistance in carrying out this study.

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